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No. 07-35

In The Supreme Court of the United States

APOTEX, INC., APOTEX CORP., and NOVEX PHARMA,

Petitioners,

v.

SYNTEX (U.S.A.) LLC and ALLERGAN, INC.,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY TO BRIEF IN OPPOSITION

Robert S. Silver
Counsel of Record
Manny D. Pokotilow
Mona Gupta
William J. Castillo
CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD
1635 Market Street
Seven Penn Center - 11th Floor
Philadelphia, Pennsylvania 19103-2212
(215) 567-2010

Counsel for Petitioners

August 20, 2007

THE LEX GROUP DC ♦ 1750 K Street, NW ♦ Suite 475 ♦ Washington, DC 20006
(202) 955-0001 ♦ (800) 815-3791 ♦ Fax: (202) 955-0022 ♦ www.thelexgroupdc.com

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I. INTRODUCTION

None of Syntex' arguments warrant denial of Apotex' Petition for Writ of Certiorari ("Petition") and, instead, show the need for a GVR order.

First, Syntex is wrong that the Federal Circuit considered and rejected Apotex' *KSR* arguments because the Federal Circuit *never* issued an opinion explaining the reasons for (1) affirming the district court's decision on remand or (2) denying Apotex' Motion to Recall and Stay the Mandate ("Motion to Recall Mandate"). Syntex merely postures that the Federal Circuit considered and rejected Apotex' *KSR* arguments but that is not sufficient to deny Apotex' Petition. The Federal Circuit's silence created an ambiguity behind its rulings. This Court explained in *Lords Landing Village Condominium Council of Unit Owners v. Continental Insurance Co.*, 520 U.S. 893, 897 (1997), which Syntex cites (Opp. 16),[1] that where a lower court makes an "ambiguous statement" about the effect of an intervening decision, that "does not establish that it actually considered and rejected petitioner's...argument" based on the intervening decision. Under such circumstance, a GVR order is appropriate. *Id.* This case is even more compelling than *Lords Landing* for the need of a GVR order because of the Federal Circuit's silence on the issue.

Second, Syntex is wrong that the district court's obviousness standard/analysis is consistent with *KSR* for the reasons stated in Apotex' Petition.

Third, Syntex is wrong that a reversal based on *KSR* would not affect the '493 dependent claims and that the secondary considerations of non-obviousness would overturn

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[1] "Opposition" and "Opp." refer to Respondents Brief in Opposition to Petition for a Writ of Certiorari. Apotex follows herein the abbreviations set forth in the Opposition at footnote 1.

any *prima facie* finding of obviousness. Since the dependent claims are not patentably distinct from the independent claims, the dependent claims would be invalid for the same reasons that the independent claims are invalid under *KSR*. Further, Apotex' obviousness case is particularly strong under *KSR* and therefore Syntex' purported evidence of secondary considerations cannot overturn the *prima facie* case.

Accordingly, Apotex' Petition should be granted.

II. REASONS FOR GRANTING PETITION

As a preliminary matter, Syntex takes out of context the arguments that Apotex' counsel made during oral argument before the Federal Circuit.[2] Syntex quotes testimony from Apotex' counsel stating that he wanted the Federal Circuit to reweigh the evidence (Opp. 7), but ignores testimony on that same page which explained that Apotex wanted the Federal Circuit to "find the clear errors that the district court made, yet again."[3] (Res. App. 3a).

Syntex is wrong that Apotex' Petition "scarcely" addressed and "fails to satisfy" the four factors for a GVR under *Lawrence v. Chater*, 516 U.S. 163, 167-68 (1996). (Opp. 10-11). Rather, pages 13-25 of the Petition demonstrate that Apotex satisfied the first three factors of

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[2] Apotex believes that it was improper for Syntex to quote the statements made during oral argument and, further, the transcription of the oral argument contains errors.

[3] Another example of Syntex misstating the record is Syntex incorrectly stating that Apotex does not appeal several underlying findings for obviousness. (Opp. 3-5). Even if Apotex' Petition did not *explicitly* cite such findings in its Petition, they are part of the appeal because they concern the underlying factual findings for obviousness.

Lawrence and pages 25-26 demonstrate that Apotex satisfied the fourth factor, as explained below.

A. There is no evidence that the Federal Circuit fully considered the *KSR* standard or Apotex' arguments based on *KSR*. (*Lawrence factor no. 1*).

Despite the Federal Circuit's silence on the issue, Syntex claims that the lower court's non-obviousness decision is consistent with *KSR* and that the Federal Circuit considered and rejected Apotex' *KSR* arguments when it denied Apotex' Motion to Recall Mandate. (Opp. 10-17). Syntex is wrong on both points because the Federal Circuit never issued an opinion in the second appeal. Thus, the reasons behind the Federal Circuit's rulings are unknown.

In support of its argument that the Federal Circuit considered and rejected Apotex' *KSR* arguments, Syntex improperly asserts that Apotex presented in its Motion to Recall Mandate the very same arguments that are presented in the Petition. (Opp. 10-11). There is no evidence that the Federal Circuit acknowledged (1) that the district court applied the correct obviousness standard under *KSR* or (2) that the district court followed the Federal Circuit's previous guidelines (*See* Pet. 9) for the obviousness inquiry. Rather, Apotex' Petition explains why the district court's decision is not in accord with *KSR* and did not follow the Federal Circuit's guidelines. (Pet. 13-23).

The unusual procedural posture and untimeliness of Apotex' Motion to Recall Mandate are most likely the reasons for the Federal Circuit's summary denial; not because it considered *KSR* on the merits as Syntex contends. After the Federal Circuit summarily affirmed the district court's decision on April 9, 2007, Apotex had until April 23, 2007 (*See* Fed. Cir. R. 35), to petition for rehearing. Apotex could not do so by then because the *KSR* decision had not issued. On April 30, 2007 the Federal Circuit issued its

mandate – the very same day that this Court rendered its decision in *KSR*. Thus, there was no way that Apotex could have timely filed a petition under *KSR*. Nor could Apotex have moved to stay the mandate before the *KSR* decision issued because Apotex had no way of knowing the outcome of *KSR*. Left with no alternative, Apotex took the extreme measure of moving for an extension of time to petition for rehearing and recalling the mandate.[4]

Syntex' attempt to distinguish *Lords Landing* fails (Res. 16-17), and instead this case supports granting a GVR order. In *Lords Landing*, after the mandate issued, petitioner moved to recall the mandate based on an intervening decision. 520 U.S. at 895. Syntex claims that a GVR order was proper in *Lords Landing* because respondent opposed the motion to recall the mandate on *procedural grounds* (rather than substantative grounds) which is "most likely" the reason for the appellate court's denial of the motion. (Opp. 16). Contrary to Syntex' assertion (*See* Opp 16-17), Syntex also opposed Apotex' Motion to Recall Mandate on procedural grounds[5] and following *Lords Landing*, a GVR

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[4] Under Fed. Cir. R. 26(b), a party seeking an extension of time generally must file its motion for extension of time, "at least 7 calendar days *before* the date sought to be extended" (emphasis added); and a motion for extension of time made after the time prescribed may be granted if warranted by "extraordinary circumstances." Having no alternative, since the *KSR* decision issued the same day as the mandate, Apotex filed an untimely motion for extension of time predicated on the existence of extraordinary circumstances.

[5] Syntex' claim that it did not oppose the Motion to Recall Mandate on procedural grounds is disingenuous. (*See* Opp. 16-17 and n.3). That is, in opposing Apotex' Motion for an Extension of Time to File Combined Petition for Panel Rehearing and Rehearing *En Banc* and Motion to Recall and Stay Mandate, Syntex argued that it was simply too late for Apotex to obtain its requested relief. Particularly, Syntex stated that while a party, "may certainly move for an extension prior to the deadline for its petition ... the Rules provide no mechanism for canceling this deadline once it has already passed." (Res. App. 41a).

order is appropriate here too.

Before the Federal Circuit could even consider the merits of Apotex' *KSR* arguments, it would have had to: (1) recall the mandate – a remedy which "is one of last resort, to be held in reserve against grave, unforeseen contingencies," *Calderon v. Thompson*, 523 U.S. 538, 550 (1998); and (2) grant an extension of time that was filed after the deadline Apotex sought to extend. In short, there were numerous procedural barriers before Apotex could be heard on the merits. It is far more likely, therefore, that the Federal Circuit denied Apotex' Motions due to untimeliness and/or the extraordinary nature of the requested relief.

Further, a GVR order is more compelling here than in *Lords Landing*.[6] In *Lords Landing*, unlike here, the appellate court at least issued an order stating that "the said petition and motions are without merit." 520 U.S. at 895. This Court nonetheless entered a GVR order because "the Court of Appeals' ambiguous statement that petitioner's request was 'without merit' does not establish that it actually considered and rejected petitioner's ... argument" based on the intervening decision. *Id.* at 896-97. Here, the Federal Circuit stood entirely silent on the effect of *KSR* and that silence creates ambiguity under *Lords Landing* because it "does not establish that it actually considered and rejected petitioner's [Apotex'] ... argument" regarding *KSR*.[7] *Id.* at 897. *See also*

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[6] A GVR order issued in *Lords Landing* despite the fact that the intervening decision actually issued before the appellate opinion issued, but the parties did not become aware of the intervening decision until after the mandate issued. 520 U.S. at 895.

[7] Syntex merely postures that the Federal Circuit considered and rejected Apotex' *KSR* arguments. This is shown by the words Syntex carefully selected to state that the Federal Circuit "*must have* rejected them [Apotex' arguments] on the merits ... [Syntex' argument that the district court's opinion already complied with *KSR*] was the only basis on (cont'd...)

Thomas v. Am. Home Prods., Inc., 519 U.S. 913, 915 (1996) (Scalia, J., concurring). Thus, a GVR order is appropriate.

B. The decision below rests upon a rigid and formalistic approach to the obviousness inquiry that the Federal Circuit would reject if given the opportunity for further consideration. (*Lawrence factor no. 2*).

For the reasons stated in Apotex' Petition (at 13-21), Syntex' response (Opp. 12-16) does not refute Apotex' strong showing that the district court's obviousness analysis was unduly rigid and formalistic and, thus, was *not* in accord with *KSR*.

Syntex alleges that in the 2006 opinions in *Alza v. Mylan* and *DyStar v. C.H. Patrick*, the Federal Circuit applied a flexible obviousness approach that was consistent with *KSR*. (Opp. 18-19). However, Syntex then makes the implausible argument that because the Federal Circuit allegedly applied the *KSR* standard in *Alza* and *DyStar*, it necessarily follows that the Federal Circuit applied the *KSR* standard here by affirming the district court. (Opp. 18). This logic defies common sense and is wrong for the reasons stated above and in the Petition.

Further, petitions for writ of certiorari have recently been filed where the parties argue that the Federal Circuit did not follow *KSR*. For example, in *DyStar v. C.H. Patrick*

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which the Court of Appeals *could have* denied Apotex' motion" (emphasis added). (Opp. 16-17). Another example of Syntex' posturing:

> The Court of Appeals denied Apotex's motion to recall the mandate, which can only mean that it was convinced that nothing in *KSR* affected the standards that it had already applied in affirming the district court. (Opp. 10).

(which Syntex claims is consistent with *KSR*), DyStar petitioned for a writ of certiorari arguing that the Federal Circuit violated *KSR* and asked in the alternative for a GVR order so that the Federal Circuit could apply *KSR* to the facts.[8] Similarly, following the decision in *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369 (Fed. Cir. 2006), both defendant-appellants petitioned for GVR orders arguing that the Federal Circuit imposed rigid requirements that are inconsistent with *KSR*.[9] Also, combined petitions for panel rehearing and rehearing *en banc* have been recently filed where again the parties argue that the Federal Circuit's opinion is inconsistent with *KSR*.[10] Thus, there is absolutely no merit to Syntex' argument that the Federal Circuit's recent decisions have been consistent with *KSR*.

Should the Federal Circuit be given an opportunity to reevaluate the district court decision in light of *KSR*, it would in all likelihood come down with a different decision.

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[8] *DyStar Textilfarben GmbH & Co. v. C.H. Patrick Co.*, 464 F.3d 1356 (Fed. Cir. 2006), *petition for cert. filed*, 2007 WL 1495834, *9 (U.S. May 21, 2007) (No. 06-1207, Reply Brief).

[9] *See* petitions for writ of certiorari filed in *Eli Lilly v. Zenith Goldline*, 2007 WL 1685850 (U.S. June 7, 2007) (No. 06-1642) and 2007 WL 1850384 (U.S. June 26, 2007) (No. 06-1723).

[10] *See* combined petitions filed in *Janssen Pharmaceutica N.V. v. Mylan Pharms., Inc.*, 2007 WL 1428462 (Fed. Cir. June 19, 2007), *combined petition for panel reh'g and reh'g enbanc filed*, 2007 WL 1787076 (Fed. Cir. May 25, 2007) (Nos. 07-1021, 07-1055) and *Takeda Chemical Indus., Ltd., v. Alphapharm Pty., Ltd.*,---F.3d---, 2007 WL 1839698 (Fed. Cir. June 28, 2007), *combined petition for panel reh'g and reh'g en banc filed*, 2007 WL 2312474 (Fed. Cir. July 12, 2007) (No. 06-1329).

C. A GVR order will change the ultimate outcome of the litigation because a reevaluation of the facts will likely show that all of the claims of the '493 patent are invalid for obviousness. (*Lawrence factor no. 3*).

1. The dependent claims of the '493 patent would be invalid for the same obviousness reasons that the independent claims are invalid.

Syntex has not identified any patentable feature in any of the '493 patent dependent claims and, instead, relies on the district court's erroneous opinion that the dependent claims disclose different inventions than the other claims. (Opp. 22). Apotex has consistently demonstrated that the additional elements of the dependent claims of the '493 patent do not impart any additional patentability to the claims and are "mere optimizations or preferred embodiments" of the independent claims.

It was proper to group the claims together because the ultimate issue at trial and on appeal – whether it was obvious to use O_{40} in the claimed formulations and whether O_{40} produced "unexpected results" – relates to both the independent and dependent claims of the '493 patent. *See Dayco Products, Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1370 (Fed. Cir. 2003) ("[I]t is permissible to group claims together for the disposition where resolution involves the same issues of validity; however, the justification for such grouping is possible only where those issues are substantially materially identical."). Accordingly, a reevaluation of the facts under *KSR* would show that the dependent claims of the '493 patent are obvious for the same reasons that the independent claims, from which they depend, are obvious. Thus, a GVR order will likely change the ultimate outcome of the litigation.

2. Syntex' purported secondary considerations of non-obviousness would not overturn the strong *prima facie* showing of obviousness of the '493 patent.

As a last resort, Syntex argues that its alleged secondary considerations of non-obviousness would overcome any *prima facie* showing of obviousness and, therefore, the "ultimate outcome of this litigation would" not be different should the Federal Circuit find a *prima facie* case of obviousness under *KSR*. (Opp. 23-24). Even if *KSR* does not directly affect the district court's findings regarding secondary considerations, Apotex' *prima facie* case of obviousness under *KSR* is particularly strong such that the secondary considerations cannot overcome the obviousness of the '493 patent. Further, each secondary consideration raised by Syntex (Opp. 24) is essentially unsubstantiated or non-existent for the reasons explained in the Petition or Apotex' opening and reply Appellate Briefs ("Op. Br." and "Reply Br.," respectively) in this case.

There is no commercial success because the evidence does not show the requisite nexus and the district court did not properly analyze Syntex' prior patents which precluded others from the relevant market in view of *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364 (Fed. Cir.), *cert. denied*, 126 S. Ct. 488 (2005). (Op. Br. 35-38; Reply Br. 19-21). The license to Allergan is not probative' because the evidence does not show the requisite nexus. *See SIBIA Neurosciences Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1358-59 (Fed. Cir. 2000) (mere existence of licenses are insufficient to overcome obviousness). There was no long felt need for the alleged '493 invention because such a need is measured from the point of view of others in the industry, not Syntex' internal needs. *Markman v. Lehman*, 987 F. Supp. 25, 43 (D.D.C. 1997), *aff'd*, 178 F.3d 1306 (Fed. Cir. 1998). There are no unexpected results from using O_{40} in the

'493 patent formulations. (Pet. 21-23; Op. Br. 29-35; Reply Br. 17-19).

Accordingly, a GVR order will likely change the ultimate outcome of the litigation and Syntex' purported secondary considerations evidence would not overturn the *prima facie* showing of obviousness of the '493 patent.

D. The equities in the case strongly favor issuing a GVR order. (*Lawrence factor no. 4*).

Apotex has explained that the equities strongly favor a remand so that the lower court can properly re-evaluate the record in light of *KSR*. (Pet. 25-26). Accordingly, Apotex has satisfied all four requirements under *Lawrence* and a GVR order is appropriate in this case.

III. CONCLUSION

Accordingly, Apotex respectfully requests that the Court grant its Petition and issue a GVR order.

Respectfully submitted,

August 20, 2007 By: /s/

Robert S. Silver
Manny D. Pokotilow
Mona Gupta
William J. Castillo
CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.
1635 Market Street
Seven Penn Center – 11th Floor
Philadelphia, PA 19103-2212
Telephone: (215) 567-2010
Facsimile: (215) 751-1142

Attorneys for Petitioners
Apotex, Inc., Apotex Corp.,
and Novex Pharma